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Examiner: Suba Ganesan

Atty. Docket No.: 101896-662 (DEP5055)

## AMENDMENTS TO THE CLAIMS

- 1. (Previously Presented) An anterior method for implanting an artificial disc in an intervertebral space of the human body, comprising:
- a) fixing a position of a midline marker such that a portion of the midline marker embeds in a face of a vertebral body to mark a midline thereof;
- b) inserting a distraction instrument into the intervertebral space using the midline marker as a guide;
  - c) selecting an artificial disc for implantation; and
- d) inserting the artificial disc in the intervertebral space using the midline marker as a guide.
- 2. (Original) The anterior method of claim 1, further comprising verifying a disc for artificial disc implantation.
- 3. (Original) The anterior method of claim 2, wherein verifying a disc for artificial disc implantation includes:

centering a verification instrument on the disc;

inserting at least one radiopaque pin extending from the verification instrument into the disc;

visualizing via X-ray the radiopaque pin in the disc; and removing the verification instrument from the disc after visualization.

4. (Original) The anterior method of claim 3, further comprises:

inserting the midline marker in a guide of the verification instrument; and impacting a proximal end of the midline marker until the midline marker is embedded in the face of the vertebral body.

- 5. (Canceled)
- 6. (Previously Presented) The anterior method of claim 1, wherein preparing the disc for artificial disc implantation includes:

removing a window from the annulus of the disc, where the window is the width of

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an artificial disc implant; and

removing a nucleus pulposus of the disc.

7. (Previously Presented) The anterior method of claim 1, wherein selecting an artificial disc for implantation, includes:

distracting the intervertebral space with a distraction instrument;

inserting at least one trial spacer into the distracted intervertebral space with a trial spacer insertion instrument, the trial spacer instrument guided into the intervertebral spacer by the distraction instrument; and

removing the trial spacer insertion instrument from the intervertebral space.

8. (Previously Presented) The anterior method of claim 7, further comprises:

contacting the trial spacer insertion instrument with a midline marker insertion instrument;

inserting the midline marker in the face of the vertebral body with the midline marker insertion instrument while being guided by the trial spacer insertion instrument; and removing the midline marker insertion instrument from the midline marker.

- 9. (Previously Presented) The anterior method of claim 1, further comprises shaping adjacent endplates of the vertebral bodies which define the intervertebral space with an endplate shaping instrument being guided by the midline marker.
- 10. (Original) The anterior method of claim 9, wherein the step of shaping adjacent endplates of the vertebral bodies, comprises:

aligning an endplate shaping instrument with the midline marker; inserting shaping blades of the endplate shaping instrument into the intervertebral

shaping the adjacent endplates of the vertebral bodies with the shaping blades.

11. (Canceled)

space; and

12. (Previously Presented) The anterior method of claim 1, wherein implanting the artificial disc in the intervertebral space includes:

inserting endplates of the artificial disc into the intervertebral space using an endplate

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insertion instrument, the endplate insertion instrument guided by the distraction instrument;

removing the distraction instrument from the intervertebral space, thereby allowing the endplates of the artificial disc to engage vertebral endplates;

inserting a core between the endplates of the artificial disc using a core insertion instrument, the core insertion instrument guided by the endplate insertion instrument; removing the core insertion instrument from the endplate insertion instrument; and removing the endplate insertion instrument from the intervertebral space.

- 13. (Previously Presented) The anterior method of claim 12, wherein inserting a core between the endplates further includes securing the core between the endplates of the artificial disc with a retention clip.
- 14. (Withdrawn) A kit for implanting an artificial disc in an intervertebral space of the human body, comprising: artificial disc insertion instruments for implanting the artificial disc into the prepared intervertebral space; and a midline marker for guiding the artificial disc insertion instruments into the prepared intervertebral space.
- 15. (Withdrawn) The kit of claim 14, wherein the site preparation instruments include a verification instrument, the verification instrument comprising: a radiolucent body, the body having a proximal end and a distal end; a handle at the distal end of the body; and at least one radiopaque pin at the proximal end of the body.
- 16. (Withdrawn) The kit of claim 15, wherein the verification instrument further comprises a guide on a surface on the body for mating with a midline marker insertion instrument.
- 17. (Withdrawn) The kit of claim 14, wherein the artificial disc insertion instruments include: a distraction instrument for distracting the intervertebral space; a trial spacer insertion instrument and various trial spacer heads for inserting into the distracted intervertebral space; an endplate insertion instrument for inserting endplates of the artificial disc into the distracted intervertebral space; and a core insertion instrument for inserting a core between the endplates of the artificial disc.

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18. (Withdrawn) The kit of claim 17, wherein the distraction instrument includes: a body element; superior and inferior arms coupled to the body; and a centering feature in at least one arm adapted to align with a midline marker.

- 19. (Withdrawn) The kit of claim 17, wherein the various trial spacer heads include: a radiolucent body having superior and inferior surfaces; diametrically opposing grooves on the superior and inferior surfaces, each groove for maintaining a centered position on superior and inferior arms of the distraction instrument; and radiopaque pins within the radiolucent body for X-ray visualization.
- 20. (Withdrawn) The kit of claim 17, wherein the endplate insertion instrument includes: a body element; and a pair of diametrically opposing arms coupled to the body, each arm having guides for mating with the distraction instrument and the core insertion instrument.
- 21. (Withdrawn) The kit of claim 17, wherein the artificial disc insertion instruments further include a core trial instrument.
- 22. (Withdrawn) The kit of claim 17, wherein the core insertion instrument includes: a body element; and guides on superior and inferior surfaces of the body, each guide for maintaining a centered position on superior and inferior arms of the endplate insertion instrument.
- 23. (Withdrawn) The kit of claim 17, further including: an endplate shaping instrument, the endplate shaping instrument having at least one centering feature for capturing the midline marker.
- 24. (Withdrawn) The kit of claim 17, further including: a retention clip insertion instrument for securing the core to an endplate of the artificial disc; and a retention clip removal instrument for removing the core form the endplate of the artificial disc.
- 25. (Withdrawn) A verification instrument for determining a disc for artificial disc replacement, comprising: a radiolucent body, the body having a proximal end and a distal end; a handle at the distal end of the body; and at least one radiopaque pin at the proximal end of the body.

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26. (Withdrawn) The verification instrument of claim 25, wherein the at least one radiopaque pin includes a first portion extending horizontally from the proximal end of the body and a second portion extending vertically within the proximal end of the body.

- 27. (Withdrawn) The verification instrument of claim 25, wherein the verification instrument further comprises a guide on a surface of the radiolucent body.
- 28. (Withdrawn) The verification instrument of claim 27, wherein the guide is selected from the group consisting of a slot and a bore.
- 29. (Withdrawn) A midline marker for providing instrument alignment and artificial disc placement, comprising: a body element, the body element having a proximal end and a distal end; and at least two protrusions, parallel to each other and forming the distal end of the body element.
- 30. (Withdrawn) The midline marker of claim 29, further including retention spikes extending from the attachment end of the body element.
- 31. (Withdrawn) An endplate shaping device, comprising: a frame, the frame having a proximal end and a distal end; a handle coupled to the proximal end of the frame; a driving mechanism, the driving mechanism disposed within the frame; two cutting shafts, each cutting shaft having a proximal end and a distal end, the proximal end of each shaft separately coupled to a pivot block on the driving mechanism and rotatable around their points of attachment, and the distal end of each cutting shaft extending from the distal end of the frame; and a pair of cutter blades, each cutter blade coupled to a respective distal end of each cutting shaft.
- 32. (Withdrawn) The endplate shaping device of claim 31, further comprising a spreader shaft slidably disposed between the two cutting shafts and extending from the proximal end of the frame.
- 33. (Withdrawn) The endplate shaping device of claim 32, wherein the spreader shaft includes: a rod having a proximal end and a distal end; a fork element coupled to the distal end of the rod; a roller assembly coupled between the fork element; and a locking pushbutton for locking of the rod within the frame.

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34. (Withdrawn) The endplate shaping device of claim 33, further including discrete graduations on the rod to determine the distance between the cutter blades.

- 35. (Withdrawn) The endplate shaping device of claim 31, further comprising at least one centering feature located on a distal end of the frame for mating with the midline marker.
- 36. (Withdrawn) A distraction instrument, comprising: a body element; a pair of diametrically opposing arms coupled to the body, at least one arm including a centering feature adapted to align with a midline marker; and a distraction mechanism movably coupled between the diametrically opposing arms.
- 37. (Withdrawn) The distraction instrument of claim 36, wherein the pair of diametrically opposing arms are removably coupled to the body.
- 38. (Withdrawn) An endplate insertion instrument, comprising: a body element; a pair of diametrically opposing arms coupled to the body, the arms having first and second opposed surfaces respectively having first and second opposed alignment surfaces; an endplate holder coupled to one end of each arm; a handle portion coupled to an opposite end of the arm; and a mounting plate, each arm slidably coupled to opposite ends of the mounting plate.
- 39. (Withdrawn) The endplate insertion instrument of claim 38, wherein the endplate holder includes an alignment feature.
- 40. (Withdrawn) The endplate insertion instrument of claim 38, wherein the endplate holder is removably coupled to the arm.
- 41. (Withdrawn) A core insertion instrument, comprising: a body element, the body having a handle end and an insertion end; and a pair of diametrically opposing guides on opposing surfaces of the insertion end.
- 42. (Withdrawn) The core insertion instrument of claim 41, wherein the insertion end is removably coupled to the body.
- 43. (Withdrawn) The core insertion instrument of claim 41, wherein the guides are removably coupled to the insertion end.

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44. (Withdrawn) A trial spacer head for determining a correct-sized artificial disc, comprising: a body element having superior and inferior surfaces; diametrically opposing grooves on the superior and inferior surfaces of the body; and radiopaque pins within the radiolucent body for X-ray visualization.

- 45. (Withdrawn) The trial spacer head of claim 44, wherein the body element comprises a radiopaque agent.
- 46. (Withdrawn) The trial spacer head of claim 44, wherein the radiopaque pins include two pairs of diametrically opposed radiopaque pins for determining alignment via X-ray.
- 47. (Withdrawn) The trial spacer head of claim 44, wherein one radiopaque pin of the pair of radiopaque pins has a greater diameter than the other radiopaque pin.
- 48. (Withdrawn) The trial spacer head of claim 44, wherein one radiopaque pin of the pair of radiopaque pins has a greater length than the other radiopaque pin.
- 49. (Withdrawn) A trial spacer head for determining a correct size of an artificial disc, the head comprising a composite comprising a radiolucent material and a radiopaque material.
- 50. (Withdrawn) The head of claim 49 wherein the radiolucent material is a polymer.
- 51. (Withdrawn) The head of claim 49 wherein the radiopaque material is barium sulfate.
- 52. (Withdrawn) A midline marker for providing instrument alignment and artificial disc placement, comprising: a body element having a proximal end and a distal end, at least one protrusion forming the distal end of the body element, and a mating feature provided on the proximal end for mating with an insertion instrument.
- 53. (Withdrawn) The marker of claim 52 comprising a single protrusion.
- 54. (Previously Presented) An anterior method for implanting an artificial disc in an intervertebral space of the human body, comprising:
- a) fixing a position of a midline marker such that a portion of the midline marker embeds in a face of a vertebral body;

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b) inserting a distraction instrument into the intervertebral space using the midline marker as a guide;

- c) selecting an artificial disc for implantation; and
- d) inserting the artificial disc in the intervertebral spacing using the midline marker as a guide, further comprising:

inserting endplates of the artificial disc into the intervertebral space using an endplate insertion instrument, the endplate insertion instrument guided by the distraction instrument;

removing the distraction instrument from the intervertebral space, thereby allowing the endplates of the artificial disc to engage vertebral endplates;

inserting a core between the endplates of the artificial disc using a core insertion instrument, the core insertion instrument guided by the endplate insertion instrument; removing the core insertion instrument from the endplate insertion instrument; and

removing the endplate insertion instrument from the intervertebral space.

- 55. (Previously Presented) The anterior method of claim 54, wherein inserting a core between the endplates further includes securing the core between the endplates of the artificial disc with a retention clip.
- 56. (Previously Presented) An anterior method for implanting an artificial disc in an intervertebral space of the human body, comprising:
- a) fixing a position of a midline marker such that a portion of the midline marker embeds in a face of only a single vertebral body;
- b) inserting a distraction instrument into the intervertebral space using the midline marker as a guide;
  - c) selecting an artificial disc for implantation; and
- d) inserting the artificial disc in the intervertebral spacing using the midline marker as a guide.

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- 57. (Previously Presented) The anterior method of claim 56, further comprising verifying a disc for artificial disc implantation.
- 58. (Previously Presented) The anterior method of claim 57, wherein verifying a disc for artificial disc implantation includes:

centering a verification instrument on the disc;

inserting at least one radiopaque pin extending from the verification instrument into the disc;

visualizing via X-ray the radiopaque pin in the disc; and removing the verification instrument from the disc after visualization.

59. (Previously Presented) The anterior method of claim 58, further comprises:
inserting the midline marker in a guide of the verification instrument; and
impacting a proximal end of the midline marker until the midline marker is embedded
in the face of the single vertebral body.

60. (Previously Presented) The anterior method of claim 56, wherein preparing the disc for artificial disc implantation includes:

removing a window from the annulus of the disc, where the window is the width of an artificial disc implant; and

removing a nucleus pulposus of the disc.

61. (Previously Presented) The anterior method of claim 56, wherein selecting an artificial disc for implantation, includes:

distracting the intervertebral space with a distraction instrument;

inserting at least one trial spacer into the distracted intervertebral space with a trial spacer insertion instrument, the trial spacer instrument guided into the intervertebral spacer by the distraction instrument; and

removing the trial spacer insertion instrument from the intervertebral space.

62. (Previously Presented) The anterior method of claim 61, further comprises:

contacting the trial spacer insertion instrument with a midline marker insertion instrument;

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inserting the midline marker in the face of the single vertebral body with the midline marker insertion instrument while being guided by the trial spacer insertion instrument; and removing the midline marker insertion instrument from the midline marker.

- 63. (Previously Presented) The anterior method of claim 56, further comprises shaping an endplate of the single vertebral body and an adjacent endplate of an adjacent vertebral body which define the intervertebral space with an endplate shaping instrument being guided by the midline marker.
- 64. (Previously Presented) The anterior method of claim 63, wherein the step of shaping the endplate of the single vertebral body and the adjacent endplate of the adjacent vertebral body, comprises:

aligning an endplate shaping instrument with the midline marker; inserting shaping blades of the endplate shaping instrument into the intervertebral space; and

shaping the endplate of the single vertebral body and the adjacent endplate of the adjacent vertebral body with the shaping blades.

65. (Previously Presented) The anterior method of claim 56, wherein implanting the artificial disc in the intervertebral space includes:

inserting endplates of the artificial disc into the intervertebral space using an endplate insertion instrument, the endplate insertion instrument guided by the distraction instrument;

removing the distraction instrument from the intervertebral space, thereby allowing the endplates of the artificial disc to engage vertebral endplates;

inserting a core between the endplates of the artificial disc using a core insertion instrument, the core insertion instrument guided by the endplate insertion instrument;

removing the core insertion instrument from the endplate insertion instrument; and removing the endplate insertion instrument from the intervertebral space.

66. (Currently Amended) The anterior method of claim [[12]] 56, wherein inserting a core between the endplates further includes securing the core between the endplates of the artificial disc with a retention clip.